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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,898	11/28/2000	Leroy Hood	P-IS 4403	7808

41552 7590 11/15/2005

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EXAMINER

MILLER, MARINA I

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/724,898

Applicant(s)

HOOD ET AL.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6-9,11,13,15,16,65,70-80,90,95-104,138,139,141 and 143-189 is/are pending in the application.
- 4a) Of the above claim(s) 143 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6-9,11,13,15,16,65,70-80,90,95-104,138,139,141 and 144-189 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' submission filed on 9/12/2005 is acknowledged. Claims 1, 6-9, 11, 13, 15-16, 65, 70-80, 90, 95-104, 138-139, 141, and 143-189 are pending. Claim 143 is withdrawn again from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention (carrier waves), there being no allowable generic or linking claim. Applicants elected species without traverse, as stated in the office action mailed 7/3/2003.

Claims 10, 12, 14, 17-64, 66-69, 81-89, 91-94, 105-137, 140, and 142 are cancelled.

Claims 1, 6-9, 11, 13, 15-16, 65, 70-80, 90, 95-104, 138-139, 141, and 144-189 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

#### ***Claim Rejections - 35 USC § 101***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6-9, 11, 13, 15-16, and 154-162 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims were rejected in the previous office action mailed 3/11/2005 as being directed to non-statutory subject matter. Applicants argue in their response filed 9/12/2005 that the instant claims are directed to statutory subject matter that has a practical utility. (p. 15 of the response). Applicants further argue that the instant "methods are useful for determining whether an individual has a health state similar to that of the reference population" and can be used for

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prediction a health state,” and therefore “specification provides sufficient description and guidance that the claimed methods produce a useful, concrete, and tangible result and accomplishes a practical application.” The applicants’ arguments seem to be directed to the issue of patentable utility and not to the issues of statutory subject matter. The examiner did not reject the instant claims for lack of patentable utility, and applicants have not specifically addressed whether the claimed method has a useful, concrete, and tangible result, which would satisfy statutory subject matter requirement under 35 U.S.C. 101. *See* MPEP § 2106. For the reasons stated above and in the previous office action, the rejection of claims 1, 6-9, 11, 13, 15-16, and 154-162 under 35 U.S.C. 101 is maintained.

***Claim Rejections - 35 USC § 112***

***Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-9, 11, 13, 15-16, 65, 70-80, 90, 95-104, 138-139, 141, and 144-189 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 65, 90, 138, 141, and 144 recite the limitation “a multidimensional coordinate point” representing multiple expression levels of multiple molecules. It is not clear whether “the expression levels of said n molecules” represented by a single “point” is intended to mean a single expression level of each of “n” molecules of an individual or multiple expression levels of each of “n” molecules of an individual. As the intended limitation is not clear, claims 1, 6-9, 11, 13, 15-16, 65, 70-80, 90, 95-104, 138-139, 141, and 144-189 are indefinite.

***Claim Rejections - 35 USC § 102***

Claims 1, 6-8, 11, 13, 15-16, 65, 70-72, 75, 77, 79-80, 90, 95-96, 99, 101, 103-104, 138-139, and 141 were rejected in the previous office action under 35 U.S.C. 102(e) as being anticipated by Friend, U.S. Patent 6,324,479.

Claims 1, 6-8, 11, 13, 15-16, 65, 70-72, 75, 77, 79-80, 90, 95-96, 99, 101, 103-104, 138-139, and 141 were rejected in the previous office action under 35 U.S.C. 102(e) as being anticipated by Friend, U.S. 2001/0018182.

Claims 1, 6-16, 65, 70-80, 90, 95-104, 138-139, 141, and 144-153 were rejected in the previous office action under 35 U.S.C. 102(b) as being anticipated by Prashar, WO 99/57130.

Claims 65, 70-72, 75, 77, 80, 90, 95-96, 99, 101, and 104 were rejected in the previous office action under 35 U.S.C. 102(a) as being anticipated by Levine, U.S. Patent 6,020,135.

Claims 1, 6-9, 11, 13, 15-16, 65, 70-73, 75, 77, 79-80, 90, 95-07, 99, 101, 103-104, 138-139, 141, 144-149, and 152-153 were rejected in the previous office action under 35 U.S.C. 102(a) as being anticipated by Bao, U.S. Patent, 6,251,601.

Applicants amended the instant claims and requested the reconsideration of the Declaration submitted by Drs. Hood and Siegel on 11/16/2004.

The Declaration was considered in the previous office action mailed 3/11/2005 (*see* p. 8-9). However, because the instant claims were amended, the examiner reconsidered the Declaration and found the arguments presented by the applicants in the response filed 9/12/2005 and the Declaration filed 11/16/2004 persuasive. The previous prior art rejections under 35 U.S.C. 102 are withdrawn.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller  
Art Unit 1631

MM

**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
*11/1/05*